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Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

[Docket Nos. 1996P-0418, 1997P-0197, 1998P-0203, and 2000N-0504]

Dear Sir or Madam:

I am writing in response to the Food and Drug Administration's proposed rule on *Salmonella* Enteritidis in shell eggs. I am an egg producer with operations in Texas**.** I take pride in delivering a quality product to my customers. The safety of our product is of utmost importance to me as an egg producer and small business operator. I encourage the FDA to review medical information from the Centers for Disease Control, which finds egg quality assurance programs have already made a difference wherever they have been used. Producers and states have been implementing these plans voluntarily, with no federal mandate.

I am already regulated by many different federal and state agencies. Even when the aim of regulation is good, the burden of complying can be unbearable, especially on farms and other small businesses. I respectfully urge FDA to minimize the additional burden:

1. **Recognize and reward what states and the industry are already doing.** FDA should thoroughly review all existing state and private egg quality assurance programs to see if they already provide protection equivalent to what FDA is seeking. If so, then producers who are in compliance with one of these plans should be considered to be in compliance with FDA's regulations.
2. **Carry out inspections and enforcement through federal and state agencies that already regulate our industry.** The Agricultural Marketing Service already inspects egg packing facilities four times a year under the Shell Egg Surveillance Program, often in cooperation with state agencies. AMS and the states are knowledgeable of the egg industry, and using them will avoid diverting FDA employees away from homeland security, import inspections and other work.

I would also suggest that FDA needs more input from scientists who are experts in egg and poultry science. Several parts of the proposal should be changed because they are either impractical, unnecessarily costly or in conflict with sound science.

?? **The proposed rule does nothing to encourage vaccination,** even though it is a highly effective means of controlling SE. I suggest that producers have the ability to demonstrate the effectiveness of a vaccination program,

and if they can do so, then they should be able to follow a protocol of a single environmental test shortly before depopulation.

- **FDA does not give any indication whether it has surveyed existing laboratories to find out whether they can handle the increased testing workload** as a result of this proposed rule. Before implementing the rule, FDA should survey public and private laboratories to assess whether lab capacity is adequate, especially in case of an outbreak of avian influenza, exotic Newcastle disease, or another serious animal illness.
- **FDA's biosecurity requirements should be more flexible.** Biosecurity is important, but the extensive steps the agency lists will be extremely burdensome on smaller farms, especially off-line contract farms. Along with other costs, these requirements could cause further consolidation in our industry, with some smaller operations unable to afford the additional labor and compliance costs. Yet our government always professes to be concerned about increasing concentration in agriculture.
- **Has FDA surveyed processors to see whether they are willing to accept eggs from SE-positive flocks?** In the years since FDA first began working on egg safety, more and more egg processors have arranged for dedicated sources of egg production, on-site or off-site, so their need to buy eggs on the open market is less to begin with. If eggs from SE-positive flocks could not be sold at any price, then the loss to producers would be much more than FDA has estimated and might require the regulation to be submitted to Congress under the unfunded mandates law. One way for FDA to address this problem would be through an indemnity system, payable if producers have fully complied with the regulatory requirements.

Our farms are adamant about delivering a fresh and safe product to our customers. We always strive to comply with the law and regulations that govern us. We must have regulations that are flexible, reasonably applied, and scientifically based, if we are to survive as a business. In agriculture, we cannot easily pass on increased costs to our customers. The producer often ends up absorbing much of the cost of regulations. I sincerely urge you to make the needed changes requested by producers, so that this regulation can be a workable and positive measure for our customers and our industry.

Sincerely,

David Elbel
Vice President